NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MEDEVA PHARMA SUISSE A.G., WARNER CHILCOTT PHARMACEUTICALS INC., and WARNER CHILCOTT COMPANY, LLC,	:	
Plaintiffs,	:	Civil Action No. 07-5165 (FLW)
v.	:	**OPINION**
ROXANE LABORATORIES, INC.,	:	
Defendant.	:	

WOLFSON, United States District Judge:

Presently before the Court is an appeal by Plaintiffs Medeva Pharma Suisse, A.G., Warner Chilcott Pharmaceuticals Inc., and Warner Chilcott Company ("Plaintiffs" or "Medeva") from an Order, dated July 8, 2010 (the "July 8 Order") by the Magistrate Judge, denying Plaintiffs' request for a modification of the Discovery Confidentiality Order ("DCO") regarding certain of Defendant Roxane Laboratories Inc.'s ("Defendant" or "Roxane") reports and in vivo testing. Plaintiffs argue that this Court should vacate the July 8 Order because the Magistrate Judge used the wrong legal standard when she determined that Plaintiffs bore the burden of establishing a reason for modifying the DCO. In response, Defendants contend that the Magistrate Judge's ruling is entitled to great deference and should not be reversed under the abuse of discretion standard because the Magistrate Judge properly determined, under the correct legal standard, that Plaintiffs bore the burden of establishing a reason for disclosure. The Court has considered the

parties' moving, opposition, and reply papers. For the reasons that follow, the Court grants Plaintiffs' Appeal and will vacate the Magistrate Judge's July 8 Order and remand for further consideration consistent with this Opinion.

I. PROCEDURAL HISTORY AND BACKGROUND

Because the facts of this case are well known to the parties, the Court will only briefly recite the relevant facts herein.

On October 26, 2007, Plaintiffs filed suit against Defendant for patent infringement. Plaintiffs allege that Defendant has willfully infringed on United States Patent No. 5,541,170 ("the '170 Patent'") relating to the treatment of inflammatory bowel diseases such as ulcerative colitis. The patent is owned by plaintiff Medeva Pharma Suisse AG, and licensed exclusively to Proctor and Gamble Pharmaceuticals, Inc. ("P&G"). The '170 Patent relates to the formulation of the active ingredient mesalamine, by which a core of mesalmine is specially coated for release to the afflicted gastrointestinal tissues. The '170 patent claims a tablet formulation of mesalamine which includes a coating that releases the entire dose of mesalamine "to the right side of the colon" so that it acts topically to relieve symptoms. P&G markets the drug ASACOL under the '170 Patent to treat mild to moderate ulcerative colitis. This case was precipitated by Defendant's 2007 filing of an Abbreviated New Drug Application ("ANDA"). The infringement issue in this case centers on whether Defendant's proposed tablet formulation releases its mesalamine dose in accordance with the claim whether the claimed invention would have been obvious to a person of ordinary skill in the art.

On May 21, 2008, the Magistrate Judge entered a DCO to protect the parties from disclosure

of proprietary business information that could do harm to each party's business advantage. The DCO is structured as an "umbrella" protective order wherein the producing party is permitted to designate certain materials as "Confidential" or "Highly Confidential." Moreover, the DCO "allocates to the producing party the burden of justifying the confidentiality designation." DCO at 3. In addition, the DCO provides that no party to the litigation is "precluded from (a) claiming that any CONFIDENTIAL or HIGHLY CONFIDENTIAL Material is not entitled to the protection of this Discovery Confidentiality Order; (b) applying to the Court for an Order permitting the disclosure or use of documents, things or information otherwise prohibited by this Discovery Confidentiality Order; or (c) applying for an Order modifying this Discovery Confidentiality Order in any respect." DCO at ¶ 27.

On April 7, 2010, Plaintiffs requested leave to modify the DCO to permit disclosure of the following documents to the Food and Drug Administration ("FDA"): (1) the expert report of Dr. Erik Sandefer, dated December 21, 2009, and all associated exhibits; (2) the expert report of Dr. Larry Augsburger, dated December 22, 2009, and all associated exhibits; (3) the expert report of Dr. Alan Safdi, dated December 22, 2009, and all associated exhibits; (4) the expert report of Dr. Carmelo Cuffari, dated December 22, 2009, and all associated exhibits; and (5) Roxane's protocol for A Scintigraphic Evaluation of a Radiolabeled and Non-Radiolabeled Delayed Release Mesalamine (DRM) Formulation in Healthy Male Subjects, dated February 10, 2010. Between April and June 2010, the parties extensively briefed the issue for the Magistrate Judge. On July 8, 2010, the Magistrate Judge issued a Letter Order denying Plaintiffs' request for relief. She held that because Roxane had properly designated the material as "Highly Confidential" under the DCO as "proprietary information that could do harm to the Designating Party's

business advantage" or "confidential research and/or development information," DCO ¶ 6, the burden shifted to Plaintiffs to establish a "compelling reason for their disclosure." July 8 Order at 2. Further, the Magistrate Judge found that Plaintiffs had failed to meet this burden and cited Bristol-Myers Squibb v. Rhone-Poulenc Rorer, Inc., 1999 U.S.Dist. LEXIS 1529 at *12 (S.D.N.Y. Feb. 11, 1999), in support of her decision. Specifically, the Magistrate Judge explained: (1) that the FDA's regulations did not require the submission of these reports; and (2) that Plaintiffs failed to show that the in vivo testing related to public health and safety.

Thereafter, on July 22, 2010, Plaintiffs filed the instant appeal of the Magistrate Judge's July 8 Order.

II. DISCUSSION

A. Standard of Review

A Magistrate Judge may "hear and determine any [non-dispositive] pretrial matter pending before the court." Cardona v. Gen. Motors Corp., 942 F.Supp. 968, 971 (D.N.J.1996) (quoting 28 U.S.C. § 636(b)(1)(A)); see also Fed. R. Civ. P. 72(a). A court will only reverse a magistrate judge's decision on a non-dispositive issue if it is "clearly erroneous or contrary to law." 28 U.S.C. § 636(b)(1)(A); Fed. R. Civ. P. 72(a); L. Civ. R. 72. 1(c)(1)(A). A magistrate judge's finding is clearly erroneous when, although there may be some evidence to support it, the reviewing court, after considering the entirety of the evidence, "is left with the definite and firm conviction that a mistake has been committed." Dome Petroleum Ltd. v. Employers Mut. Liab. Ins. Co., 131 F.R.D. 63, 65 (D.N.J.1990) (quotations omitted). "A district judge's simple disagreement with the magistrate judge's findings is insufficient to meet the clearly erroneous

standard of review." Andrews v. Goodyear Tire & Rubber Co., Inc., 191 F.R.D. 59, 68 (D.N.J.2000) (citations omitted).

In contrast, "the phrase 'contrary to law' indicates plenary review as to matters of law." Haines v. Liggett Group, Inc., 975 F.2d 81, 91 (3d Cir.1992); accord In re Human Tissue Products Liability Litigation, No. 06-135(WJM), 2009 WL 1097671, * 1 (D.N.J. Apr.23, 2009) (citation omitted). See also, Mruz v. Caring, Inc. , 166 F. Supp.2d 61, 66 (D.N.J.2001) ("[T]his Court will conduct a de novo review of a Magistrate Judge's legal conclusions."); accord Cooper Hosp./Univ. Med. Ctr. v. Sullivan, 183 F.R.D. 119, 127 (D.N.J.1998). "A ruling is contrary to law if the magistrate judge has misinterpreted or misapplied applicable law." Kounelis v. Sherrer, 529 F. Supp.2d 503, 518 (D.N.J.2008) (citing Gunter v. Ridgewood Energy Corp., 32 F. Supp.2d 162, 164 (D.N.J.1998)). "The burden of demonstrating clear error rests with the appealing party." Sensient Colors, 649 F. Supp. 2d at 315 (citing Kounelis, 529 F.Supp.2d at 518).

B. July 8, 2010 Order

In the instant matter, Plaintiffs argue that the Magistrate Judge erroneously relied on Bristol-Myers Squibb, 1999 U.S. Dist. LEXIS 1529, at *11-12, when she ruled that Plaintiffs failed to meet their burden to establish a compelling reason for the modification of the DCO. In Bristol Myers Squibb, the Southern District of New York held that a party seeking to disclose to the FDA testimony and documents otherwise governed by a protective order must show a "compelling need or extraordinary circumstances for declassification." Id. at *8 (emphasis added)(citing Martindell v. International Telephone & Telegraph Corp., 594 F.2d 291, 296 (2d

Cir. 1979) and Palmieri v. State of New York, 779 F.2d 861, 866 (2d Cir.1985)). However, the Third Circuit has expressly rejected this stringent standard for the modification of a confidentiality order. Pansy v. Borough of Stroudsburg, 23 F.3d 772,789 (3d Cir. 1994). Indeed, the Pansy court explained, "the standard of the Court of Appeals for the Second Circuit for modification is too stringent. The appropriate approach in considering motions to modify confidentiality orders is to use the same balancing test that is used in determining whether to grant such orders in the first instance, with one difference: one of the factors the court should consider in determining whether to modify the order is the reliance by the original parties on the confidentiality order." Id. at 790.

In Glenmede Trust Co v. Thompson, the Third Circuit summarized the factors to be weighed in making a good cause determination as follows: (1) whether disclosure will violate any privacy interests; (2) whether the information is being sought for a legitimate or an improper purpose; (3) whether disclosure of the information will cause a party embarassment; (4) whether confidentiality is being sought over information important to public health and safety; (5) whether the sharing of information among litigants will promote fairness and efficiency; (6) whether a party benefitting from the order of confidentiality is a public entity or official; and (7) whether the case involves issues important to the public. 56 F.3d 476, 483 (3d Cir. 1995).

Moreover, at least one court in this district has explained that the Pansy inquiry "does not state a burden-shifting approach . . . Rather, the burden rests only on the party seeking protection to show that there is good cause for it. The Court determines whether good cause exists by conducting a balancing analysis." Robotic Parking Systems Inc., v. City of Hoboken, Civ. A. No. 06-3419(SRC), 2010 WL 1077286, at *2 (D.N.J. March 23, 2010).

In the instant matter, the Magistrate Judge expressly cited the "compelling need" standard set forth in Bristol Myers Squibb. July 8, 2010 Order at 2. Specifically, she explained that "the burden . . . therefore shifts to Plaintiffs for establishing a compelling reason for their disclosure." Id. (emphasis added). Although the Magistrate Judge cited the Second Circuit standard, she also appears to have considered several of the balancing test factors enumerated by the Third Circuit in Glenmede Trust Co., 56 F.3d at 483. Thus, it is unclear what standard the Magistrate Judge applied in denying Plaintiffs' request for modification of the DCO. Accordingly, the Court will vacate the July 8 Order and remand for further consideration with instructions to not apply the burden shifting or compelling need tests and, instead, to apply the entirety of the Third Circuit's balancing test.

III. CONCLUSION

For the foregoing reasons, Plaintiffs' Appeal is GRANTED, the July 8, 2010 Order is VACATED and this matter is REMANDED for further consideration in light of the foregoing opinion.

Dated: January 24, 2011

/s/ Freda L. Wolfson
Freda L. Wolfson, U.S.D.J.